

IN THE CLAIMS:

Please amend claims 1 and 22 as follows and cancel claims 3 and 25 without prejudice or disclaimer of subject matter. The following is a complete listing of claims and replaces all prior versions and listings of claims in the present application.

1. (Currently Amended) An intravaginal drug delivery device for administration into a vaginal environment, the device comprising at least one reservoir, the at least one reservoir containing at least one pharmacologically active agent or a prodrug thereof, dispersed in a hydrophobic elastomeric polymer; and a hydrophobic elastomeric sheath discontinuously surrounding the at least one reservoir so as to define one or more holes or openings, each hole or opening extending through the sheath to the at least one reservoir, ~~so that, in use, at least part of the at least one reservoir is directly exposed to the vaginal environment,~~

wherein each hole or opening is substantially cylindrical with a diameter in the range of about 0.5 to 6.5 mm, ~~so that, in use, at least part of the at least one reservoir is directly in contact with the vaginal environment~~ and the total surface area of the reservoir ~~exposed to in contact with~~ the vaginal environment through the one or more holes or openings, when in use, is in a range of 1 to 750mm<sup>2</sup>,

wherein the sheath is impermeable to the at least one pharmacologically active agent or the prodrug thereof,

wherein the at least one pharmacologically active agent or the prodrug thereof is released from the hydrophobic elastomeric polymer ~~of the at least one reservoir through the surface area of the reservoir that is exposed to directly in contact with~~ the vaginal environment, and

wherein the drug has a molecular weight greater than 400 Daltons and is delivered at a pharmaceutically acceptable rate.

2 - 5. (Cancelled)

6. (Previously Presented) The intravaginal drug delivery device according to Claim 1, in which the at least one hole or opening extends through the sheath substantially normal to the reservoir surface.

7. (Previously Presented) The intravaginal drug delivery device according to Claim 1, in which the device is a ring that is substantially circular in transverse cross-section, and the at least one hole or opening extends substantially radially through the sheath at the inner circumference of the ring or at outer circumference of the ring.

8. (Previously Presented) The intravaginal drug delivery device according to Claim 7, in which there are one to thirty of said holes or openings along the inner or outer circumference of the intravaginal drug delivery device.

9. (Previously Presented) The intravaginal drug delivery device according to Claim 1, in which the device is a substantially cylindrical rod device, and said at least one hole or opening is provided at each terminal end of the rod.

10. (Previously Presented) The intravaginal drug delivery device according to Claim 9, in which the rod device defines a right circular cylinder and each base of the rod is partly or fully exposed, to define said holes.

11. (Previously Presented) The intravaginal drug delivery device according to Claim 9, in which further holes or openings are provided extending substantially radially through the sheath.

12. (Previously Presented) The intravaginal drug delivery device according to Claim 11, in which there are one to thirty of said further holes or openings, along the circumference of the rod.

13. (Previously Presented) The intravaginal drug delivery device according to Claim 1, in which the device is a partial or complete toroid shape.

14. (Previously Presented) The intravaginal drug delivery device according to Claim 1, in which the reservoir additionally comprises at least one pore-forming excipient.

15. (Previously Presented) The intravaginal drug delivery device according to Claim 14, in which the pore-forming excipient comprises a water-soluble or water-swelling polysaccharide, a monosaccharide or a disaccharide, water-soluble salt, a protein, a nonionic surface active agent, a bile salt, an organic solvent, or a fatty acid ester.

16. (Previously Presented) The intravaginal drug delivery device according to Claim 1, in which the sheath comprises at least one additional pharmacologically active agent.

17.-18. (Cancelled)

19. (Previously Presented) The intravaginal drug delivery device according to Claim 1, wherein a daily release rate of the drug is in the order of milligrams per day.

20. (Previously Presented) The intravaginal drug delivery device according to Claim 1, wherein the drug is relatively hydrophilic.

21. (Cancelled)

22. (Currently Amended) A method of delivering a drug having a molecular weight of greater than 400 Daltons at a pharmaceutically suitable rate from an intravaginal drug delivery device, the method comprising administering the intravaginal drug delivery device into a vaginal environment, the device comprising at least one reservoir, the at least one reservoir containing at least one pharmacologically active agent or a prodrug thereof, dispersed in a hydrophobic elastomeric polymer; and a hydrophobic elastomeric sheath discontinuously surrounding the at least one reservoir so as to define one or more holes or openings, each hole or opening extending through the sheath to the at least one reservoir, so that, in use, at least part of the at least one reservoir is directly exposed to the vaginal environment,

wherein each hole or opening is substantially cylindrical with a diameter in the range of about 0.5 to 6.5 mm, so that, in use, at least part of the at least one reservoir is directly in contact with the vaginal environment and the total surface area of the reservoir exposed to in contact with the vaginal environment through the one or more holes or openings, when in use, is in a range of 1 to 750mm<sup>2</sup>,

wherein the sheath is impermeable to the at least one pharmacologically active agent or the prodrug thereof, and

wherein the at least one pharmacologically active agent or the prodrug thereof is released from the hydrophobic elastomeric polymer of the at least one reservoir through the surface area of the reservoir that is exposed to directly in contact with the vaginal environment.

23. (Previously Presented) The method of claim 22, in which the drug is relatively hydrophilic.

24. (Previously Presented) The method of claim 22, in which the intravaginal drug delivery device has a daily release rate of the drug in the order of milligrams per day.

25. (Cancelled)